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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/697,908 | 10/29/2003 | Jon Faiz Kayyem | A-67499-2/RMS/RMK/SPL/463 | 9212 |

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| EXAMINER | |
|---|---|
| LU, FRANK WEI MIN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1634 | |

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/697,908 | KAYYEM, JON FAIZ | |
| | Examiner | Art Unit | |
| | Frank W Lu | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.



JWC

## DETAILED ACTION

### *Response to Amendment*

1. Applicant's response to the office action filed on January 13, 2005 has been entered. The claims pending in this application are claims 1-9. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn.

### *Specification*

2. The disclosure is objected to because of the following informality: since case 09/472,657 in the first sentence of the specification now is US Patent No. 6,833,267 B1 (issued on December 21, 2004), applicant is required to update the information for the case 09/472,657 in the first sentence of the specification.

Appropriate correction is required.

### *Claim Objections*

3. Claim 1 is objected to because of the following informalities: no period should appear after the label of each step, e.g., "a." should be --a)--.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Duong *et al.*, (US Patent No. 6,740,518 B1, priority date: September 17, 1998).

The applied reference has a common inventor, Jon Faiz Kayyem with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Duong *et al.*, teach a method of determining the presence of target analytes in a sample comprising: a) applying said sample to an array comprising a plurality of electrodes, wherein at least one electrode comprises an assay complex comprising: i) a capture binding ligand covalently attached to said electrode; ii) a target analyte; and iii) an electron transfer moiety wherein each electrode comprises a self-assembled monolayer; b) applying an input waveform to said electrode to generate an output waveform comprising at least one harmonic component, having a harmonic number greater than or equal to two; c) detecting said output waveform at said electrode; and d) analyzing said harmonic component with harmonic number greater than or equal to two to determine the presence of said target analytes (see column 109, claim 1 and column 10, second paragraph).

Regarding claim 1, since Duong *et al.*, teach applying an input waveform to said electrode to generate an output waveform comprising at least one harmonic component, having a

harmonic number greater than or equal to two wherein said electrode in circuit boards in an injection molded sample chamber comprises an assay complex comprising: i) a capture binding ligand covalently attached to said electrode; ii) a target analyte; and iii) an electron transfer moiety wherein each electrode comprises a self-assembled monolayer after hybridization (see column 10, second paragraph, columns 101-103, and column 109, claim 1), Duong *et al.*, disclose applying an initial signal (ie., an input waveform) to a tissue collection device (ie., the injection molded sample chamber containing a circuit board, see column 103) comprising an electrode comprising a self-assembled monolayer and an assay complex comprising a capture binding ligand, said target analyte, and an electron transfer moiety as recited in claim 1. Since Duong *et al.*, teach detecting said output waveform at said electrode and analyzing said harmonic component with harmonic number greater than or equal to two to determine the presence of said target analytes (see column 109, claim 1) and the input and output signals taught by Duong *et al.*, are used to measure electron transfer of electron transfer moiety, Duong *et al.*, disclose detecting electron transfer between said electrode and said electron transfer moiety as recited in claim 1.

Regarding claim 2, Duong *et al.*, teach that said sample is blood (see column 5, lines 19-38).

Regarding claims 3 and 4, Duong *et al.*, teach that said self-assembled monolayer comprises insulators and an EFS (see columns 12 and 13).

Regarding claim 5, Duong *et al.*, teach that said target analyte is nucleic acid (see column 109, claim 2).

Regarding claim 6, Duong *et al.*, teach that said capture binding ligand is a capture probe (see column 26, lines 47-60).

Regarding claim 7, Duong *et al.,* teach that said assay complex comprises a label probe comprising said electron transfer moiety (see column 37, lines 26-52).

Regarding claim 8, Duong *et al.,* teach that said electron transfer moiety is ferrocene (see column 41).

Therefore, Duong *et al.,* teach all limitations recited in claims 1-8.

***Response to Arguments***

In page 6, third paragraph of applicant's remarks, applicant argues that "[T]he specification states that a 'tissue collection device' is any container, generally capable of being sealed, that can be used to collect, contain or store tissues, including bodily fluids (Specification at page 6, lines 4-5). Duong *et al.* does not teach or suggest a 'tissue collection device' and hence, Duong et al. does not anticipate these claimed subject matter".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. Since Duong *et al.,* teach to hybridize nucleic aids on the electrodes of the circuit boards in an injection molded sample chamber to a target nucleic acid in a sample and detecting the hybridization by measuring an output waveform (ie., the output current) (see column 103) and the injection molded sample chamber is a container that can be used to collect, contain or store tissues, Duong *et al.*, teach a tissue collèction device (ie., the injection molded sample chamber).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duong *et al.,* (September 17, 1998) as applied to claims 1-8 above, and further in view of Furse (US Patent No. 5,354,483, published on October 11, 1994).

The teachings of Duong *et al.,* have been summarized previously, *supra.*

Duong *et al.,* do not disclose that said tissue collection device further comprises an evacuated tube as recited in claim 9.

Furse teaches that the pre-evacuated blood collection tube has the following advantages: once sterilized, its interior remains sterile without additional packaging; simplicity of structure and use, in that its basic form consists of only a glass tube permanently closed at one end with a rubber stopper in the open end; and it is self-sealing when blood drawing is complete and the cannula which was used to puncture the rubber stopper has been removed (see column 1, lines 63-67 and column 2, lines 1-6).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a tissue collection device comprising an evacuated tube as recited in claim 9 in view of the prior art of Duong *et al.,* and Furse. One having ordinary skill in the art would have been motivated to do so because addition of an evacuated tube into the tissue collection device recited in claim 1 would prevent cross-contamination when collected sample is blood (see claim 2) and using an evacuated tube for collecting blood "has the following advantages: once sterilized, its interior remains sterile without additional packaging; simplicity of structure and use, in that its basic form consists of

only a glass tube permanently closed at one end with a rubber stopper in the open end; and it is self-sealing when blood drawing is complete and the cannula which was used to puncture the rubber stopper has been removed" (see Furse, column 1, lines 63-67 and column 2, lines 1-6). One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to add an evacuated tube into the tissue collection device recited in claim 1 when he or she requires to obtain a target analyte from a blood sample.

***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1 and 5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, and 13 of U.S. Patent No. 6,7,40,518 B1 in view of Rubinstein *et al.,* (US Patent NO. 5,108,573, published on April 28, 1992).

Regarding claims 1 and 5, steps a) and b) of claim 1 of U.S. Patent No. 6,740,518 B1 teaches applying a sample to an array comprising a plurality of electrodes and applying an input waveform to said electrode to generate an output waveform. Since U.S. Patent No. 6,740,518 B1 indicates that a circuit board comprising a plurality of electrodes (ie., the array) is in an injection molded sample chamber (see columns 102 and 103) and the specification in this instant application defines "tissue collection device" as any container, generally capable of being sealed, that can be used to collect, contain or store tissues, including bodily fluids (see specification at page 6, lines 4-5), steps a) and b) of claim 1 of U.S. Patent No. 6,740,518 B1 must disclose applying an initiation signal (ie., an input waveform) to a tissue collection device comprising an electrode as recited in step a) of claim 1 of this instant application. Since U.S. Patent No. 6,7,40,518 B1 indicates that AC input (ie., an initiation signal) and output waveforms are used to detect electron transfer (see columns 96 and 97), steps c) and d) of claim 1 and claim 13 of U.S. Patent No. 6,740,518 B1 teach b) of claim 1 in this instant application. Claim 2 of U.S. Patent No. 6,740,518 B1 teaches all limitations of claim 5 of this instant application.

Claims 1, 2, and 13 of U.S. Patent No. 6,740,518 B1 do not disclose a self-assembled monolayer as recited in claim 1 of this instant application.

Rubinstein *et al.,* teach that the molecules of a self-assembled monolayer on a metal electrode facilitate and regulate the bonding between the modified metal surface and the growing phase of the conducting polymer (see column 4, lines 16-30).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have formed the method recited in claim 1 of this instant application by incorporating a self-assembled monolayer into an array complex recited in claim 1

in view of claims 1, 2, and 13 of U.S. Patent No. 6,7,40,518 B1 and Rubinstein *et al.*. One having ordinary skill in the art has been motivated to do so because incorporation of a self-assembled monolayer on a metal electrode would facilitate and regulate the bonding between the modified metal surface of the electrode and a conducting polymer (see Rubinstein *et al.*, column 4, lines 16-30). One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to incorporating a self-assembled monolayer into an array complex recited in claim 1 in view of claims 1, 2, and 13 of U.S. Patent No. 6,7,40,518 B1 and Rubinstein *et al.*.

***Response to Arguments***

In page 7, last paragraph bridging to page 8, second paragraph of applicant's remarks, applicant argues that "[C]laims 1, 2, and 13 of Duong et al. and the claims of Rubinstein et al. neither teach nor suggest applying an initiation signal to a tissue collection device comprising an electrode".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. Since steps a) and b) of claim 1 of U.S. Patent No. 6,740,518 B1 teaches applying a sample to an array comprising a plurality of electrodes and applying an input waveform to said electrode to generate an output waveform, and U.S. Patent No. 6,7,40,518 B1 indicates that a circuit board comprising a plurality of electrodes (ie., the array) is in an injection molded sample chamber (see columns 102 and 103) and the specification in this instant application defines "tissue collection device" as any container, generally capable of being sealed, that can be used to collect, contain or store tissues, including bodily fluids (see specification at page 6, lines 4-5), steps a) and b) of claim 1 of U.S. Patent No. 6,7,40,518 B1 must disclose applying an initiation

signal (ie., an input waveform) to a tissue collection device comprising an electrode as recited in step a) of claim 1 of this instant application.

10. Claims 1, 5, and 8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/714,489. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims in this instant application is either anticipated by, or would have been obvious over, the reference claims. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). Although claims 1, 5, and 13 in this instant application are not identical to claims 1-25 of copending Application No. 10/714,489, claims 1, 5, and 8 in copending Application No. 10/714,489 are directed to the same subject matter and fall entirely within the scope of claims 1, 5, and 8 in this instant application. In other words, claims 1, 5, and 8 in this instant application are anticipated by claims 1-25 of copending Application No. 10/714,489. Note that, since the case 10/714,489 indicates that a circuit board comprising a plurality of electrodes (ie., the array) is in an injection molded sample chamber (see pages 122 and 123) and the specification in this instant application defines "tissue collection device" as any container, generally capable of being sealed, that can be used to collect, contain or store tissues, including bodily fluids (see specification at page 6, lines 4-5), claim 1 of 10/714,489 must

disclose applying an initiation signal (ie., an input waveform) to a tissue collection device comprising an electrode as recited in of claim 1 of this instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

11. No claim is allowed.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
March 31, 2005

FRANK LU
PATENT EXAMINER